AMERICAN
SOCIETY FOR
MICROBIOLOGY

Public and Scientific Affairs Board

October 25, 2005

Mr. Donald W. Jehn
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852

RE: Blood Products Advisory Committee Meeting, November 3-4, 2005
Approaches to OTC home-use HIV test kits

Dear Mr. Jehn:

The American Society for Microbiology (ASM) appreciates the opportunity to provide comments to the Blood Products Advisory Committee (BPAC) for its consideration of "approaches to over-the-counter (OTC) home-use HIV test kits" during its November 3, 2005 meeting. The ASM is the largest scientific society dedicated to the advancement of the microbiological sciences and their application for the common good. The Society represents more than 42,000 individual members who work as researchers, educators, clinicians, administrators and technical personnel in academic, industry, government, clinical and public health laboratories and institutions.

According to the Clinical Laboratory Improvement Amendments (CLIA) of 1988, the criteria that waived tests must meet include:

- They employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible.

- They pose no reasonable risk of harm to the patient if the test is performed incorrectly.

Certain lateral flow immunochromatography assays for HIV-1 antibodies have already been granted waived status by the Food and Drug Administration (FDA). The FDA has recognized the inherent difficulties in having non-trained individuals perform HIV testing by adding stringent quality assurance requirements to the tests that are already waived. Since the same criteria can not be applied in cases where an individual is performing the test themselves, the ASM believes strongly that these tests should meet even stiffer criteria before they can be considered for home use. These criteria should evaluate the likelihood of erroneous interpretation of test results and the risk of harm to patients if test results are interpreted incorrectly.

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Home HIV-1 antibody testing will remove the responsibilities for assay results interpretation and patient counseling from trained medical professionals. Even if patients are advised to seek professional advice by the package insert for the test, there will be financial disincentives for doing so. Such consequences cannot be justified in the name of increased access to testing.

It is our contention that erroneous or incorrect interpretation of HIV-1 antibody test results by lay persons not only presents a reasonable risk of harm to patients, but presents a significant risk of harm to society at large. Falsely negative results interpretation generates a mistaken sense of well-being that will delay the initiation of beneficial antiretroviral therapy for patients and leads to preventable infection of others. Falsely positive results interpretation unnecessarily distresses uninfected patients who will certainly experience severe anxiety as well as financial and productivity loss, secondary to the seeking of medical care. In a worst case scenario, they may become severely depressed or suicidal.

Dr. Patricia Charache of the Johns Hopkins Medical Institutions and representing the ASM, will elaborate on these points, as well as several others during the public comment portion of the BPAC Meeting.

Thank you for your consideration of our comments.

Sincerely,

Joseph M. Campos

Joseph M. Campos, Ph.D., Chair
Committee on Laboratory Practices
Public and Scientific Affairs Board